



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,322	04/05/2001	Laurent Schaller	6835-60067 (0800195-46)	5639
<div>7590 07/13/2007 Jeffrey J. Hohenshell, Esq. Medtronic, Inc. 7601 Northland Drive Brooklyn Park, MN 55428</div>			<div>EXAMINER PATEL, NIHIR B</div> <div>ART UNIT 3772</div> <div>PAPER NUMBER</div>	
			<div>MAIL DATE 07/13/2007</div> <div>DELIVERY MODE PAPER</div>	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

87

Office Action Summary	Application No.	Applicant(s)	
	09/828,322	SCHALLER ET AL.	
	Examiner	Art Unit	
	Nihir Patel	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 25th, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 31-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-38 is/are allowed.
- 6) ☒ Claim(s) 1-6, 20, 24-26, 39-44, 47-51, 54 and 55 is/are rejected.
- 7) ☒ Claim(s) 7-19, 21-23, 45, 46, 52 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5.3.04; 12.14.04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on March 21st, 2007, with respect to claims 1-26 and 31-55 have been fully considered and are persuasive. The rejection(s) of the previous office action has been withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **1-6, 20, 24-26, 39-43, 47, 48-50, 54 and 55** are rejected under 35 U.S.C. 102(b) as being anticipated by Sander (US 5,374,268).

4. **As to claim 1**, Sander teaches a device and method for repairing torn tissue that comprises two clips **14 (see figure 1; see column 3 lines 50-60)**, each sized and shaped to attach tissues and hold the tissues together therein (**see column 5 lines 5-20**), and bridge portion **16** connecting the two clips and spacing the clips from one another (**see figure 1; see column 3 lines 55-65**).

5. **As to claim 2**, Sander teaches an apparatus wherein the bridge portion is substantially straight (**the material used to manufacture the bridge portion is flexible and therefore is substantially straight**).

6. As to **claim 3**, Sander teaches an apparatus wherein the two clips have an open configuration and a closed configuration (**when the Sander's is in closed position, the clips 14 are close together and when the clips are in the open position the clips are spread apart**).

7. As to **claim 4**, Sander teaches an apparatus wherein the bridge portion provides a predetermined spacing between the clips in the closed configuration (**see figure 4**).

8. As to **claim 5**, Sander teaches an apparatus wherein at least one of the two clips is a self closing clips (**in Sander's reference both clips are self closing when they are inserted in the tissue**).

9. As to **claim 6**, Sander teaches an apparatus wherein the self-closing clip comprises shape memory material (**the bridge portion is flexible and there for has shape memory material**).

10. As to **claim 39**, Sander teaches an apparatus wherein each of the clips has a memory set loop configuration and a deformed configuration, and the bridge portion separates the loops from one another when the clips are in their memory set configuration (**see figures 1 and 4**).

11. As to **claim 40**, Sander teaches an apparatus wherein each of the clips has a free end (**see figure 1**).

12. As to **claim 20**, Sander teaches a device and method for repairing torn tissue that comprises a surgical fastener comprising two clips 14 (**see figure 1 and column 3 lines 50-60**); and shaped to attach tissues and hold the tissue therein including at least one self-closing clip having an open configuration and a closed configuration (**see figure 4**), wherein the open configuration is a biased configuration and the closed configuration is an unbiased configuration, and a bridge portion 16 (**see figure 1 and see column 3 lines 50-60**) having a substantially straight portion connecting the two clips (**the material used to manufacture the bridge portion**

is flexible and therefore is substantially straight); and a release mechanism (the bridge portion is also defined as a release mechanism) having a first position to bias the self-closing clip in the open configuration, and a second position to unbias the self-closing into the closed configuration (see figures 1 and 4).

13. As to claim 24, Sander teaches a device and method for repairing torn tissue that comprises a surgical fastener having two ends including a first end and a second end (see figure 1) and including two clips (see column 3 lines 45-55) sized and shaped to attach tissues including at least one self-locking clip (in Sander's reference both clips are self closing when they are inserted in the tissue), and a substantially straight bridge portion 16 (see figure 1 and column 3 lines 50-60) connecting the two clips; and two tissue piercing members including a first tissue piercing member 13 releasably coupled to the first end and a second tissue piercing member releasably coupled to the second end (see figure 1).

14. As to claim 25, Sander teaches an apparatus that further comprises a release mechanism (the bridge portion is also defined as a release mechanism), and wherein the release mechanism activates the release of the two piercing members from the respective two ends (see figures 1 and 4).

15. As to claim 26, Sander teaches an apparatus wherein the release mechanism activates the closing of the self-closing clip (see figures 1 and 4).

16. As to claim 41, Sander teaches a device and method for repairing torn tissue that comprises an elongated member having a first loop shaped portion adapted to hold tissue therein (see figure 2), a second loop shaped portion adapted to hold tissue therein (see figure 2), and a bridge portion 16 (see figure 2) bridging the first and second loop shaped portions (see figure 2),

Art Unit: 3772

each loop shaped portion having a free end being deformable into a second deformed shape where it tends to return towards its loop shape **(see figures 2 and 6)**.

17. **As to claim 42**, Sander teaches an apparatus wherein the elongated members are not coils **(see figure 2)**.

18. **As to claim 43**, Sander teaches an apparatus wherein the elongated member is a wire **(see figure 2)**.

19. **As to claim 47**, Sander teaches an apparatus wherein the bridge portion **16** is substantially straight **(the material used to manufacture the bridge portion is flexible and therefore is substantially straight)**.

20. **As to claim 48**, Sander teaches a device and method for repairing torn tissue that comprises an elongated member **(see figure 2)** having a first loop shaped portion, a second loop shaped portion **(see figure 2)** and a bridge portion **16 (see figure 2)** bridging the first and second loop shaped portions **(see figure 4)**, each loop shaped portion having a piercing element **(see figure 2)** at one end and a portion the merges into the bridge shaped portion, each loop shaped portion being deformable into a second deformed shape and having the property of tending to return towards its loop shape **(see figures 1 and 4)**.

21. **As to claim 49**, Sander teaches an apparatus wherein the elongated members are not coils **(see figure 2)**.

22. **As to claim 50**, Sander teaches an apparatus wherein the elongated member is a wire **(see figure 2)**.

Art Unit: 3772

23. As to **claim 54**, Sander teaches an apparatus wherein the bridge portion **16** is substantially straight (**the material used to manufacture the bridge portion is flexible and therefore is substantially straight**).

24. As to **claim 55**, Sander teaches a device and method for repairing torn tissue that comprises two clips **14** (see **figures 1 and column 3 lines 45-55**) and a bridge portion **16** (see **figure 1 and column 3 lines 50-60**) connecting the two clips (see **figures 1**) having a piercing element **13** (see **figure 1**) at one end thereof.

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

26. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

27. Claims **44 and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander (US 5,374,268).

28. As to **claims 44 and 51**, Sander substantially teaches an apparatus; see rejection of claims 41 and 48, but does not disclose an apparatus wherein the wire is made from nitinol. It

Art Unit: 3772

would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Sander's invention by providing a wire that is made from nitinol in order to make it safer for the patient, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

29. Claims **31-38** are allowed. The prior art does not disclose a pair of coils, one of the coils surrounding at least a portion of one of the first loop shaped portion and the other of the coils surrounding at least a portion of the second loop shaped portion.

30. Claims **7-19, 21-23, 45, 46, 52 and 53** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose a pair of coils, one of the coils surrounding at least a portion of one of the first loop shaped portion and the other of the coils surrounding at least a portion of the second loop shaped portion.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 3772



Nihir Patel



PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700